(j) Potassium-containing active ingredients:

(1) Potassium bicarbonate (or carbonate when used as a component of an effervescent preparation); maximum daily dosage limit 200 mEq. of bicarbonate ion for persons up to 60 years old and 100 mEq. of bicarbonate ion for persons 60 years or older.

(2) Sodium potassium tartrate.

(k) Sodium-containing active ingredients:

(1) Sodium bicarbonate (or carbonate when used as a component of an effervescent preparation); maximum daily dosage limit 200 mEq. of sodium for persons up to 60 years old and 100 mEq. of sodium for persons 60 years or older, and 200 mEq. of bicarbonate ion for persons up to 60 years old and 100 mEq. of bicarbonate ion for persons 60 years or older. That part of the warning required by § 330.1(g), which states, ''Keep this and all drugs out of the reach of children'' is not required on a product which contains only sodium bicarbonate powder and which is intended primarily for other than drug uses.

(2) Sodium potassium tartrate.

(l) Silicates:

(1) Magnesium aluminosilicates.

(2) Magnesium trisilicate.

(m) Tartrate-containing active ingredients. Tartaric acid or its salts; maximum daily dosage limit 200 mEq. (15 grams) of tartrate.

[39 FR 19874, June 4, 1974, as amended at 51 FR 27763, Aug. 1, 1986; 55 FR 19859, May 11, 1990]

§ 331.15 Combination with nonantacid active ingredients.

(a) An antacid may contain any generally recognized as safe and effective nonantacid laxative ingredient to correct for constipation caused by the antacid. No labeling claim of the laxative effect may be used for such a product.

(b) An antacid may contain any generally recognized as safe and effective analgesic ingredient(s), if it is indicated for use solely for the concurrent symptoms involved, e.g., headache and acid indigestion, and is marketed in a form intended for ingestion as a solution.

(c) An antacid may contain any generally recognized as safe and effective antiflatulent ingredient if it is indicated for use solely for the concurrent symptoms of gas associated with heartburn, sour stomach or acid indigestion.

Subpart C—Testing Procedures

§ 331.20 Determination of percent contribution of active ingredients.

To determine the percent contribution of an antacid active ingredient, place an accurately weighed amount of the antacid active ingredient equal to the amount present in a unit dose of the product into a 250-milliliter (mL) beaker. If wetting is desired, add not more than 5 mL of alcohol (neutralized to an apparent pH of 3.5), and mix to wet the sample thoroughly. Add 70 mL of water, and mix on a magnetic stirrer at 300±30 r.p.m. for 1 minute. Analyze the acid neutralizing capacity of the sample according to the procedure provided in the United States Pharmacopeia 23/National Formulary 18 and calculate the percent contribution of the antacid active ingredient in the total product as follows:

Percent contribution = (Total mEq. Antacid Active Ingredient x100)/(Total mEq. Antacid Product).

[61 FR 4823, Feb. 8, 1996]

§ 331.21 Test modifications.

The formulation or mode of administration of certain products may require a modification of the United States Pharmacopeia 23/National Formulary 18 acid neutralizing capacity test. Any proposed modification and the data to support it shall be submitted as a petition under the rules established in § 10.30 of this chapter. All information submitted will be subject to the disclosure rules in part 20 of this chapter.

[61 FR 4823, Feb. 8, 1996]

Subpart D—Labeling

§ 331.30 Labeling of antacid products.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as an ''antacid.''

(b) *Indications.* The labeling of the product states, under the heading ''Indications,'' the following: ''For the relief of'' (optional, any or all of the following:) ''heartburn,'' ''sour stomach,''

and/or ''acid indigestion'' (which may be followed by the optional statement:) ''and upset stomach associated with'' (optional, as appropriate) ''this symptom'' or ''these symptoms.'' Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in this paragraph (b), may also be used, as provided in § 330.1(c)(2) of this chapter, subject to the provisions of section 502 of the act relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(c) *Warnings.* The labeling of the product contains the following warnings, under the heading ''Warnings'', which may be combined but not rearranged to eliminate duplicative words or phrases if the resulting warning is clear and understandable:

(1) ''Do not take more than (maximum recommended daily dosage, broken down by age groups if appropriate, expressed in units such as tablets or teaspoonfuls) in a 24–hour period, or use the maximum dosage of this product for more than 2 weeks, except under the advice and supervision of a physician.''

(2) For products which cause constipation in 5 percent or more of persons who take the maximum recommended dosage: ''May cause constipation.''

(3) For products which cause laxation in 5 percent or more of persons who take the maximum recommended dosage: ''May have laxative effect.''

(4) For products containing more than 50 mEq. of magnesium in the recommended daily dosage: ''Do not use this product except under the advice and supervision of a physician if you have kidney disease.''

(5) For products containing more than 25 mEq. potassium in the maximum recommended daily dose: ''Do not use this product except under the advice and supervision of a physician if you have kidney disease.''

(6) For products containing more than 5 gm per day lactose in a maximum daily dosage: ''Do not use this product except under advice and supervision of a physician if you are allergic to milk or milk products.''

(d) *Drug interaction precaution.* The labeling of the product contains the following statement ''Ask a doctor or pharmacist before use if you are [bullet][1] presently taking a prescription drug. Antacids may interact with certain prescription drugs.''

(e) *Directions for use.* The labeling of the product contains the recommended dosage, under the heading ''Directions'', per time interval (e.g., every 4 hours) or time period (e.g., 4 times a day) broken down by age groups if appropriate, followed by ''or as directed by a physician.''

(f) *Exemption from the general accidental overdose warning.* The labeling for antacid drug products containing the active ingredients identified in § 331.11(a), (b), and (d) through (m); permitted combinations of these ingredients provided for in § 331.10; and any of these ingredients or combinations of these ingredients in combination with simethicone (identified in § 332.10 of this chapter and provided for in § 331.15(c)), are exempt from the requirement in § 330.1(g) of this chapter that the labeling bear the general warning statement ''In case of accidental overdose, seek professional assistance or contact a poison control center immediately.'' With the exception of sodium bicarbonate powder products identified in § 331.11(k)(1), the labeling must continue to bear the first part of the general warning in § 330.1(g) of this chapter, which states, ''Keep this and all drugs out of the reach of children.''

(g) [Reserved]

(h) The word ''doctor'' may be substituted for the word ''physician'' in any of the labeling statements in this section.

[39 FR 19874, June 4, 1974, as amended at 47 FR 38484, Aug. 31, 1982; 51 FR 16266, May 1, 1986; 51 FR 27763, Aug. 1, 1986; 52 FR 7830, Mar. 13, 1987; 55 FR 11581, Mar. 29, 1990; 58 FR 45208, Aug. 26, 1993; 59 FR 60556, Nov. 25, 1994; 61 FR 17806, Apr. 22, 1996; 64 FR 13295, Mar. 17, 1999]

[1] See § 201.66(b)(4) of this chapter.